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Pesticide Fact Sheet Number 89.2: Avermectin B1

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

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EPA

Pesticide Fact Sheet

Name of Chemical:	Avermectin B_1
Reason for Issuance:	Changed Use Pattern - Indoor Use
Date Issued:	JUL 20 1990
Fact Sheet Number:	89.2

1. Description of Chemical

Generic Name: Avermectin B_1 [A mixture of avermectins containing $\geq$ 80% avermectin B_{1a} (5-0-demethyl avermectin A_{1a}) and $\leq$ 20% avermectin B_{1b} (5-0-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_{1a})]

Common Name: Abamectin
Trade Names: Affirm , Agrimec , Avid , MK-936, Zephyr , Avert
EPA Shaughnessy Code: 0122804
Chemical Abstracts Service (CAS) Numbers: 65195-55-3 and 65195-56-4
Year of Initial Registration: 1986
Pesticide Type: Insecticide/Miticide
Chemical Family: Avermectins (macrocylic lactones isolated from soil organism (Streptomyces avermitilis).
U.S. Producers: Merck & Co., Inc.

2. Use Pattern/Formulations/and Product Limitations*

Application Sites: Garages, Homes, Non-Patient Areas of Hospitals and Nursing Homes and the Nonfood/feed Areas of Hotels, Motels, Nursing Homes, Transportation Equipment (Buses, Boats, Ships, Trains, Planes), Utilities, Warehouses, and Other Commercial and Industrial Buildings.

Type of Formulation: Whitmire Avert PT 310 Abamectin dust containing 0.05% of the active ingredient abamectin.

Method of Application: Localized spot treatment, crack and crevice treatment with hand or power duster.

* This fact sheet refers to indoor uses only. See EPA Fact Sheet 89.1 for description of other uses of products containing Abamectin.

Rate of Application: Dust lightly and uniformly to infested sites. 12-24 spot treatments (2 ft x 2 ft area) per 100 sq ft.

Limitations: For Use By Commercial Applicators. Not for use in the food/feed areas of commercial food/feed handling establishment, restaurants or other areas where food is commercially prepared or processed.

3. Science Findings

Summary Science Statement

Technical avermectin exhibits high mammalian acute toxicity. The results of the acute toxicity tests on the indoor use formulation indicates that the product is of low toxicity. It is not considered to be mutagenic and does not sensitize skin. It is not readily absorbed by mammals and the majority of the residue is excreted in the feces within 2 days. The 24-month rat chronic feeding/oncogenicity study and 94-week mouse chronic toxicity oncogenicity study were negative for oncogenic potential. The results of a series of developmental toxicity studies (rat, rabbit, mouse) have been evaluated and showed that avermec-tin B_1 produces developmental toxicity (cleft palate) in the CF_1 mouse. Toxicology data were also evaluated for the delta-8,9-isomer of avermectin B_1 which is a plant photodegradate. This isomer possess avermectin like toxicological activity. It was concluded that the delta-8,9-isomer also produces developmental toxicity (cleft palate) in mice, but not in rats.

Sufficient data are available to characterize avermectin from an environmental fate and ecological standpoint. Avermectin is extremely toxic to mammals and aquatic invertebrates and highly toxic to fish and bees. Avermectin is relatively non-toxic to birds.

Avermectin undergoes rapid photolysis, is readily degraded by soil microorganisms and, due to its binding properties and low water solubility, is expected to exhibit little or no potential for leaching.

Chemical/Physical Characteristics (Technical Grade)

Physical State: Crystalline powder
Color: Yellowish-white
Odor: Odorless
Melting Point: 155 - 157° C
Vapor Pressure: 1.5×10^{-9} torr
Density: 1.16 ± 0.05 at 21°C
Solubility: Insoluble in water ($\leq$ 5 ug/mL), readily soluble in organic solvents
pH: NA. The avermectin molecule has neither acidic nor basic functional groups
Octanol/Water Partition Coefficient: 9.9×10^3

Toxicological Characteristics

Technical Grade Avermectin B_1

- Dermal Sensitization: Negative for skin sensitization
- Acute Oral LD_{50} - Rat: 10.6 mg/kg (males), 11.3 mg/kg (females)
- 14-Week Oral Study - Rat: NOEL $\geq$ 0.4 mg/kg/day (HDT)
- 18-Week Oral Study - Dog: NOEL = 0.25 mg/kg/day
- Teratology Study - Rat: Negative for terata up to 1.0 mg/kg/day.
- Teratology Study - Rabbit: Teratogenic NOEL = 1.0 mg/kg/day.
- Teratology Studies - Mouse: Teratogenic LEL = 0.4 mg/kg/day (cleft palate); Teratogenic NOEL = 0.2 mg/kg/day.
- Maternotoxicity Studies - Mouse: LEL = 0.075 mg/kg/day (lethality); NOEL = 0.05 mg/kg/day
- 2-Generation Reproduction Study - Rat: NOEL = 0.12 mg/kg/day; LEL = 0.40 mg/kg/day (increased retinal folds in weanlings, increased dead pups at birth, decreased viability indices, decreased lactation indices, decreased pup body weights)
- 1-Year Oral Study - Dog: NOEL = 0.25 mg/kg/day; LEL = 0.50 mg/kg/day (mydriasis in males and females)
- 94-Week Chronic Toxicity/Oncogenicity Study - Mice: Oncogenic potential: Negative up to 8 mg/kg/day (HDT); Systemic NOEL = 4 mg/kg/day; Systemic LEL = 8 mg/kg/day (Dermatitis in males, extramedullary hematopoiesis in the spleen in males, increased mortality in males, tremors and body weight loss in females)
- 2-Year Chronic Toxicity/Oncogenicity Study - Rats: Oncogenic potential: Negative up to 2.0 mg/kg/day (HDT); Systemic NOEL = 1.5 mg/kg/day; Systemic LEL = 2.0 mg/kg/day tremors in both sexes)
- Metabolism Study - Rat: The metabolic T 1/2 in rats is 1.2 days
- Ames Mutagenicity Assay: Negative
- Mutagenicity Assay for Chromosomal Aberrations *in vitro* in Chinese Hamster Ovary Cells

- Rat Hepatocyte Mutagenicity Study: Under conditions of the study, abamectin (0.3 and 0.6 mM) caused an induction of single strand DNA breaks in rat hepatocytes in vitro; no effect was observed when the assay was carried out on hepatocytes from rats dosed in vivo at the LD_{50} dose level (10.6 mg/kg).

- In Vivo Bone Marrow Mutagenicity Cytogenic Study: Negative in male mice at doses of 1.2 and 12.0 mg/kg

Toxicity Studies on the Delta-8,9-Isomer of Avermectin

- Acute Oral LD_{50} - Mouse: > 80 mg/kg (HDT) (males and females)

- Teratology Study - Rat: Negative for terata up to 1.0 mg/kg/day (HDT)

- Teratology Studies - Mouse: Teratogenic LEL = 0.10 mg/kg/day (cleft palate); Teratogenic NOEL = 0.06 mg/kg/day

- Maternotoxicity Studies - Mouse: LEL = 0.50 mg/kg/day (lethality); NOEL = 0.10 mg/kg/day

- 1-Generation Reproduction Study - Rat: NOEL = 0.4 mg/kg/day (HDT)

- Ames Mutagenicity Assay: Negative

Toxicity Studies for Whitmire Formulation

Acute Oral Toxicity in Rats:	Toxicity Category IV
LD_{50} = > 5.0 g/kg	
Acute Dermal Toxicity in Rabbits:	Toxicity Category III
LD_{50} = > 2.0 g/kg	
Acute Inhalation:	Waiver Granted
LC_{50} = >	
Primary Eye Irritation in Rabbits:	Toxicity Category III
Primary Dermal Irritation in Rabbits:	Toxicity Category IV
Dermal Sensitization:	Not a sensitizer

Ecological Characteristics

Avian Oral (Bobwhite quail): LD_{50} > 2000 mg/kg; LC_{50} = 3102 ppm
Avian Dietary (Mallard duck): LC_{50} = 383 ppm
Freshwater Fish (Bluegill): LC_{50} = 9.6 ppb
Rainbow trout: LC_{50} = 3.2 ppb
Estuarine Fish (Fathead minnow): LC_{50} = 15 ppb
Oyster Embryo Larvae: LC_{50} = 430 ppb.
Acute Freshwater Invertebrate (Daphnia): LC_{50} = 0.22 ppb
Acute Estuarine Invertebrate (Shrimp, mysid): LC_{50} = 0.02 ppb

Environmental Characteristics

Avermectin is stable to hydrolysis at ph 5, 7, and 9 and thus is not expected to hydrolyze in the environment. It photodegrades rapidly in water and soil with half-lives of less than 12 hours and 1 day respectively. Soil metabolism studies conducted in darkness indicate degradatior does occur with a half-life of 2 weeks to 2 months under aerobic conditions. Anaerobic degradation is slower. It is not expected to accumulate in fish. Avermectin's solubility in water is determined ?to be 7.8 ppb. The field dissipation study indicates that avermectin, when applied directly to the soil, dissipates with a half-life of about a week but may persist longer if the pesticide is shaded. Due to its binding properties and low water solubility, Avermectin is expected to exhibit little or no potential for leaching.

Tolerance Assessment

This changed use pattern does not involve a food use and as such a tolerance assessment is not needed.

Exposure Assessment

Because of adverse developmental effects seen in animal studies, a margin of safety (MOS) for these effects (maternal toxicity and developmental toxicity) were calculated with respect to dermal exposure to applicators applying the dust product. Based upon surrogate exposure data and dermal absorption data in the monkey, the calculated MOS for applicators was found to exceed 100 in all instances. This MOS is sufficient to adequately protect these workers.

4. Summary of Regulatory Position and Rationale

The Agency has determined that it should allow the unconditional registration of abamectin for indoor use in and around homes and the nonfood/nonfeed areas of commercial establishments for control of household pests, such as ants, cockroaches, etc. Adequate data are available to assess the acute and chronic toxicological effects of abamectin to humans. Since no crop, food or feed uses are proposed a tolerance assessment is not necessary. Although technical abamectin is highly toxic to aquatic organisms (invertebrates and fish) these use patterns (indoor uses) should not pose any environmental hazard. None of the criteria for unreasonable adverse effects listed in Section 154.7(a) of Title 40 of the U.S. Code of Regulations have been met or exceeded for this use.

5. Summary of Data Gaps

There are no data gaps for this changed use pattern (non-food indoor use).

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6. Contact Person at EPA

George T. LaRocca
Product Manager 15
Insecticide-Rodenticide Branch
Registration Division (H7505C)
Office of Pesticide Program
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

Office location and telephone number:

Rm. 204, CM #2
1921 Jefferson Davis Highway
Arlington, VA 22202
(703) 557-2400

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